LUNG CANCER

A. It has not been scientifically established that smoking causes lung cancer. There are scientific data that are inconsistent with this claim, and vital questions remain unanswered about the nature of the reported relationship between smoking and lung cancer.

B. Data from epidemiological (population) studies in which smoking has been reported to be statistically associated with lung cancer mortality alone do not and, in fact, cannot prove causation.

1. Cigarette smoking is a recognized "risk factor" for lung cancer, because a statistical association exists between smoking and the occurrence of lung cancer; however, a risk factor is not the same as a cause-and-effect relationship.

   a. According to the 1964 United States Surgeon General's Report:

      > "Statistical methods cannot establish proof of a causal relationship in an association. The causal significance of an association is a matter of judgment which goes beyond any statement of statistical probability."[1]

   b. According to the 1982 United States Surgeon General's Report:

      > "The causal significance of an association is a matter of judgment

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which goes beyond any statement of statistical probability."[2]

2. The application of the criteria advanced by the 1964 United States Surgeon General's Report to determine whether the reported association between smoking and certain diseases might be causal raise a number of questions. The report listed five criteria: the consistency of the association; the strength of the association; the specificity of the association; the temporal relationship of the association; and the coherence of the association. Examples of the types of questions which have been raised regarding these criteria include the following:

   a. The wide range of relative risk ratios for lung cancer mortality for the 35 retrospective studies on lung cancer listed in the 1982 U.S. Surgeon General's Report (from 1.2 to 36.0 for men and from 0.2 to 5.3 for women) and for the mortality ratios (cigarette smokers versus nonsmokers) for the eight prospective studies (from 3.76 to 14.2 in males and from 2.3 to 5.0 in females) raise questions as to whether the criterion for "consistency" has been met.[3]

   b. The inconsistencies in the "dose-response" relationship raised questions regarding the criterion

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for "coherence" (the biological plausibility) of the association.

(1) Differences in inhalation practices among smokers are not reflected in differences in lung cancer incidence, as lower lung cancer rates have been reported among inhalers than among non-inhalers.[4]

3. The epidemiological studies have inherent limitations.

a. The study populations are not randomly selected.

(1) Smokers are "self-selected," meaning that in epidemiological studies, smokers, nonsmokers and exsmokers are divided into groups solely on the basis of their smoking habits, even though it has been reported that there are numerous differences between smokers, nonsmokers, and exsmokers in addition to their smoking habits.[5] Therefore, studies of smokers and nonsmokers made without regard for other differences are properly subject to scientific criticism.

b. The study populations are not representative.

(1) The study populations from which much of the data on smoking and health are derived have been criticized as being unrepresentative of the general population they are supposed to represent.[6]

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(2) The validity of applying the results of such studies to any population other than the study population (including applying the data to the population of another country) is open to question. This is especially relevant in connection with the application of data derived from the North American and European studies to such countries as India where the populations, climate, diet, social customs, etc., are vastly different.

c. The use of death certificate data is questionable.

(1) Much of the data in epidemiologic studies has been taken from death certificates. However, since death certificate information reportedly contains many errors,[7] the mortality statistics derived from such information may not be accurate.

d. Information biases may arise from several sources.

(1) Diagnostic problems.

(a) When presenting with similar clinical pictures, smokers are more likely to be diagnosed with lung cancer than nonsmokers.[8]

(b) Problems of "underdiagnoses" occurred before the middle of this century as

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doctors were limited in their ability to detect lung cancer because they lacked the principle diagnostic methods now being used.[9]

(c) Problems of "overdiagnosis" are evident in recent years, in part because lung cancer may be classified on death certificates as primary, or originating in the lung, when in fact the cancer originated elsewhere and then metastasized or spread to the lung to cause a secondary, or metastatic, cancer.[10]

(2) Smoking histories.

(a) Information collected from family members or friends may be inaccurate or incomplete.

4. The many inconsistencies in the epidemiological studies raise questions about a causal relationship between cigarette smoking and lung cancer.

a. There are geographic differences in consumption and disease rates. Higher lung cancer rates do not always occur in countries where more cigarettes are smoked.

(1) British cigarette consumption was lower in 1930 than in the United States, but lung cancer

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death rates in 1950 were much higher than in the U.S.[11]

b. The vast majority of even "heavy" smokers in the epidemiological studies do not develop lung cancer.[12]

c. Age at initiation of smoking is not related to age of disease onset.

(1) Nonsmokers and smokers (whether they smoke only a few or many cigarettes) all appear to develop lung cancer at about the same average age.[13]

d. There are differing mortality rates for other respiratory tract sites.

(1) Although inhaled cigarette smoke is distributed equally between both lungs, lung cancers very rarely occur simultaneously in both lungs.[14]

(2) Cancer rarely occurs in the trachea (the "windpipe"), even though this organ is exposed to more tobacco smoke than either lung.[15]

(3) There has been little change in the incidence of laryngeal cancer in many countries over the past decades, even though cigarette smoke must pass through the larynx (the "voice box") on its way to and from the lungs.[16]

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C. No biological mechanisms have been presented to explain how lung cancer is caused, whether by smoking or by any other factor.

1. Two specialists have observed:

> "Although a large number of factors have been associated with the development of malignant neoplasms [cancers] in humans, the mechanisms involved are still largely unknown."[17]

D. Animal studies do not support a causal conclusion regarding the association between cigarette smoking and lung.

1. Animal inhalation experiments, thought to provide the most relevant experimental data, have failed to show that inhalation of fresh whole tobacco smoke causes human-lung type lung cancer in animals.[18]

   a. A nine-year study in which over 10,000 mice were exposed to cigarette smoke failed to produce the type of lung cancer most strongly associated with cigarette smoking in humans.[19]

2. The results of so-called skin painting experiments in which "tar" is placed on the skin and ears of animals are not relevant to the of human experience.

   a. "Tar" is an artificially created laboratory substance, not actual cigarette smoke.

   b. Extremely high concentrations were used.[20]

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c. Such experiments are said to involve "the wrong material, in the wrong form, in the wrong concentration to the wrong tissue of the wrong animal."[21]

E. Lung cancer is a multifactorial disease -- many factors may be involved in its development.

1. Numerous factors have been associated with this disease in addition to cigarette smoking.

2. Among the most frequently mentioned risk factors are occupational exposures (specifically mining, foundry work, welding),[22] viruses,[23] diet,[24] genetics or heredity,[25] pollution,[26] depression and stress,[27] impaired body defense mechanisms,[28] diesel and gasoline exhausts,[29] and radon.[30]

F. The pathogenesis or development of lung cancer is complex; an understanding of lung cancer causation continues to elude the scientific community.

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